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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/732,983

12/10/2003

Thomas J. Holman

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6109 BLUE CIRCLE DRIVE
SUITE 2000
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,983

Applicant(s)

HOLMAN ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11,12,14 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 13, 15-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 11/20/2006 in which claims 1 and 26-27 were amended. Currently claims 1-29 are pending for examination in this application with claims 8, 9, 11, 12, 14 and 28 withdrawn from a previous election restriction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 10, 13, 15-17, 18-20 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Duchamp (6,575,934). Duchamp discloses a low profile catheter assembly.

Regarding claims 1-4, 10, 13, 15-17, 18-20 and 29, Duchamp discloses a catheter (10) comprising a proximal and distal portion, a shaft (71) having a proximal and distal portion with a conduit (86) therethrough with a longitudinal portion with a step down circumference (65) and multiple layers (71, 88) being formed of different materials, a distal tip layer (80) extending beyond the distal end of the shaft (no more than 7mm) (col 4, ln 15-30) and being formed of a tube and being positioned about the distal portion of the shaft, a medical balloon (43) having a body portion positioned between a proximal and distal waist connected (near 55) (Figures 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 21-22 are rejected under 35 U.S.C 103(a) as being unpatentable over Duchamp. Duchamp meets the claim limitations as described above except for the specific disclosed materials (col 5, 5-45).

Regarding claims 5 and 21-22, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Duchamp with the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claim Rejections - 35 USC § 103

Claims 6-7 are rejected under 35 U.S.C 103(a) as being unpatentable over Duchamp in view of Larson et al. (6,048,338). Duchamp meets the claim limitations as described above except for a spiral cut layer.

However, Larson et al. teaches a catheter with a spiral cut transition member.

Regarding claims 6-7, Larson et al. teaches catheter (200) with a multi-layer construction comprising a spiral cut member (126) (Figure 5).

At the time of the invention, it would have been obvious to add the spiral cut member of Larson et al. to the system of Duchamp in order to improve catheter flexibility and catheter tracking (col 2, ln 1-25). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Larson et al. (see abstract).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamilton et al. (6,368,301). Hamilton et al. discloses a catheter having a soft distal tip.

Regarding claims 23-25, Hamilton et al. discloses a catheter (10) having a shaft with a first (21) tubular layer and a second layer (15) comprising a medical balloon with a distal tip section (14) comprising a waist area (near 31) to which the balloon body portion overlaps (Figures 1-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-27 are rejected under 35 U.S.C 103(a) as being unpatentable over Hamilton et al. Hamilton et al. meets the claim limitations as described above except for the specific disclosed materials (col 4, 25-45).

Regarding claims 26-27, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Hamilton et al. with the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments with respect to claims 1-7, 10, 13, 15-22 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 11/20/2006 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Hamilton et al. reference (6,368,301) does not disclose a catheter with multiple layers (i.e. first and second).

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner disagrees with Applicant's Representative's assertions, the Hamilton et al. reference discloses a catheter with multiple layers (18, 21 and 15) as shown in Figures 1-2.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests adding additional structural/spatial relationship of the distal tip elements as shown in Figure 6 (elements 20, 12, and 19).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 6/7/07


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